UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,463	11/23/2005	Ying Zhang	200507001-1	3795

40079 7590 12/24/2008

YUAN QING JIANG
P.O. BOX 61214
PALO ALTO, CA 94306

EXAMINER	
HENRY, MICHAEL C	
ART UNIT	PAPER NUMBER
1623	
MAIL DATE	DELIVERY MODE
12/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,463	ZHANG ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6,8-11 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *8-11* is/are allowed.

6)☒ Claim(s) *4-6, 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 09/25/08.

The amendment filed 09/25/08 affects the application, 10/538,463 as follows:

Claims 4 and 9 have been amended. Applicants' amendments have overcome the rejections made under 35 U.S.C. 112, first paragraph. Consequently, the said rejection is withdrawn. The rejection made under 35 U.S.C. 103(a) in the prior office action mailed 06/26/08 is maintained.

The responsive to applicants' amendments is contained herein below.

Claims 4-6, 8-11, 14 are pending in application

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-6, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staack Reis Machado et al. (EP 1122259 A2) in view of Ohmoto et al. (Shoyakugaku Zasshi (1974), 28(1), pages 1-6, abstract Only).

In claim 4, applicant claims a method of extracting total triterpenoid sapogenins from bamboo comprising:

(a) selecting bamboo material from the group consisting of Phyllostachys, Bambusa and Dendrocalamus genus of Gramineae family;

(b) preparing bamboo shaving powder having a granularity from pole, branch, leaf, shoot, shoot sheath, root or a mixture of the bamboo material by comminuting the bamboo material into bamboo shaving powder;

(c) drying the bamboo shaving powder**;**

(d) extracting free triterpenoid sapogenins from the bamboo shaving powder by mixing the bamboo shaving powder with supercritical CO_2 fluid and an entrainer in the amount of 5 -15 % (v/v) of CO_2 until the free triterpenoid sapogenins is dissolved in the CO2 fluid at temperature 50 - 60 degree C and pressure 25 - 35 Mpa;

(e) separating total triterpenoid sapogenins from the CO_2 fluid containing free triterpenoid sapogenins by changing the temperature of the CO_2 fluid to 35 - 45 degree C and the pressure to 5 - 10 Mpa to gasify the CO2;

(f) collecting a composition comprising 10 - 90% total triterpenoid sapogenins, said total triterpenoid sapogenins comprising 5 - 35% friedelin and 1 - 10% lupenone. Claims 5-6 and 14 are drawn to the method of claim 4 further comprising extracting free triterpenoids sapogenins from the bamboo powder with recycled recycled CO_2 for given time, the use of specific entrainer including ethanol and the use of specific granularity.

Staack Reis Machado et al. disclose a method for extracting triterpenoids (including friedelin and related compounds) from the ceroid fraction of cork smoker wash solids comprising mixing the material with the supercritical CO_2 fluid, thereby making the low-polar substances of said material such as free triterpenoids dissolve in CO_2 fluid, wherein and the extraction temperature is between 30-50 °C and the pressure is between 4-40 Mpa (see abstract, example 1, claims). Staack Reis Machado et al. disclose that the pressure and temperature may be changed during the exraction, or may be constant, and

carries out the separation at separation temperature between 20-120 °C and pressure between 40 Mpa and atmospheric pressure (see abstract, example 1, claims). Furthermore, Staack Reis Machado et al. disclose that the co-solvent can be ethanol (see claim 5).

The difference between applicant's claimed method and the method of Staack Reis Machado et al. is that Staack Reis Machado et al. do not extract their triterpenoids from the same plant (bamboo), as applicant. However, Staack Reis Machado et al. disclose that compounds including triterpenoids can be extracted from natural origins and that supercritical fluids can be applied in the extraction of natural products (see page 2, section [0009]-[0011]). This implies that triterpenoids can be extracted or isolated from natural origins such as from plants (e.g. (bamboo plant).

Ohmoto et al. disclose a composition comprising triterpenoid sapogenins and related compounds that are extracted from bamboo (Arundinarieae) of Gramineae plants wherein said composition comprises friedelin, lupenone and other pentacyclic triterpenoids (see abstract). It should be noted that Arundinaria is a genus of bamboo commonly known as canes. Ohmoto et al. do not explicitly disclose the total % of triterpenoid sapogenins and the % of friedelin and lupenone in their composition. But, the silence of Ohmoto et al. does not mean that their composition does not contain the same said total % of triterpenoid sapogenins and % of friedelin and lupenone. Furthermore, it should be noted that Ohmoto et al.'s composition is obtained from the same source as applicant's composition and comprises the same components or substances (friedelin and lupenone) as applicant's composition and consequently may well have the same total percentages (%) of triterpenoid sapogenins and the same % of

friedelin and lupenone. Ohmoto et al. anticipates the claims if their composition has the same total percentages (%) of triterpenoid sapogenins and the same % of friedelin and lupenone. Ohmoto et al. renders the claims as being obvious if the total percentages (%) of triterpenoid sapogenins and the % of friedelin and lupenone in their composition is substantially close to the total percentages (%) of triterpenoid sapogenins and the % of friedelin and lupenone in applicant's composition.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Staack Reis Machado et al. and Ohmoto et al., to have used the method of Staack Reis Machado et al. to extract triterpenoids from any plant such as bamboo in order to use them to treat conditions such as rheumatoid diseases, based on factors such as availability, cost, convenience and/or need.

One having ordinary skill in the art would have been motivated in view of Staack Reis Machado et al. and Ohmoto et al., to use the method of Staack Reis Machado et al. to extract triterpenoids from any plant such as bamboo in order to use them to treat conditions such as rheumatoid diseases, based on factors such as availability, cost, convenience and/or need. It should be noted that a skilled artisan would be motivated to modify the physical parameters such as temperature, concentration, time and repetition or types of extractions in order to optimize the process conditions and physical variables such as amounts, % yield and/or purity of product (i.e., phytosterols). It should be noted that merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. In re Aller, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955).

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: The examiner has found claims 8-11 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. The present invention relates a method of treating hypertension, comprising administering to a subject suffering from said hypertension a therapeutically effective amount of a specific triterpenoid sapogenins composition extracted from bamboo. The invention also relates to a method of in vitro inhibiting growth of specific cancer cells or tumor cells comprising treating the cancer cells or tumor cells with a therapeutically effective amount of a specific triterpenoid sapogenins composition extracted from bamboo. The invention also relates to a method for intensifying SOD activity or reducing MDA level of the skin or hair in a subject comprising administering to a subject a therapeutically effective amount of a specific total triterpenoid sapogenins extracted from bamboo. The prior art does not teach or suggest the method of the instant invention as set forth in claims 8-11.

Response to Arguments

Applicant's arguments with respect to claim 4-6, 14 have been considered but are not found convincing.

The applicant argues that high temperature and steam cooking operation steps are necessary for Machado to prepare the raw material for extracting long chain aliphatic alcohols and diterpenoid and triterpenoid compounds. Machado is silent about preparing materials from natural origins such as plants (e.g. bamboo shaving powder having a granularity from pole, branch, leaf, shoot, shoot sheath, root or a mixture of the bamboo material) by comminuting the material into powder WITHOUT high temperature and steam cooking operation. Machado is also silent about drying step as cited by step c in

amended claim 4 of the present invention. Machado's method is, at least, different from the present invention in terms of selecting a plant of natural origin, preparing the plant of natural origin, and the substances extracted from the natural origin. However as set forth above, Staack Reis Machado et al. disclose that compounds including triterpenoids can be extracted from natural origins and that supercritical fluids can be applied in the extraction of natural products (see page 2, section [0009]-[0011]). This implies that triterpenoids can be extracted or isolated from natural origins such as from plants (e.g. (bamboo plant). Consequently, one of ordinary skill in the art would be motivated to modify the physical parameters such as temperature, concentration, time and repetition of extractions or to carry out the process continuously based on factors such as the state, condition or type of the plant material used and/or availability, cost, convenience and/or need. It should be noted that merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. In re Aller, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955). It should also be noted that the use of common conventional techniques such as drying, grinding of a starting material, reactant or product (such as a plant material) is common in the art and is well within the purview of a skilled artisan.

The applicant argues that since Machado's method uses different plant of natural origin and different preparation processes in comparison with the present invention, modifications have to be made in order to produce "a composition comprising 10 - 90% total triterpenoid sapogenins, said total triterpenoid sapogenins comprising 5 - 35% friedelin and 1 - 10% lupenone" as cited in claim 4 of the present invention. However as set forth above, Staack Reis Machado et al. disclose that compounds

including triterpenoids can be extracted from natural origins and that supercritical fluids can be applied in the extraction of natural products (see page 2, section [0009]-[0011]). This implies that triterpenoids can be extracted or isolated from natural origins such as from plants (e.g. (bamboo plant). In addition, the above rejection, was made by combining Staack Reis Machado et al. and Ohmoto et al. Thus, it should be noted that Ohmoto et al. disclose a composition comprising triterpenoid sapogenins and related compounds that are extracted from bamboo (Arundinarieae) of Gramineae plants wherein said composition comprises friedelin, lupenone and other pentacyclic triterpenoids (see abstract). Also, it should be noted that Arundinaria is a genus of bamboo commonly known as canes. Ohmoto et al. do not explicitly disclose the total % of triterpenoid sapogenins and the % of friedelin and lupenone in their composition. But, the silence of Ohmoto et al. does not mean that their composition does not contain the same said total % of triterpenoid sapogenins and % of friedelin and lupenone. Furthermore, it should be noted that Ohmoto et al.'s composition is obtained from the same source as applicant's composition and comprises the same components or substances (friedelin and lupenone) as applicant's composition and consequently may well have the same total percentages (%) of triterpenoid sapogenins and the same % of friedelin and lupenone. Ohmoto et al. anticipates the claims if their composition has the same total percentages (%) of triterpenoid sapogenins and the same % of friedelin and lupenone. Ohmoto et al. renders the claims as being obvious if the total percentages (%) of triterpenoid sapogenins and the % of friedelin and lupenone in their composition is substantially close to the total percentages (%) of triterpenoid sapogenins and the % of friedelin and lupenone in applicant's composition.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry
December 21, 2008.

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623